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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,750	03/07/2002	Philip W. Hammond	50036/050002	2879
31020	7590	05/10/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,750	Applicant(s) HAMMOND ET AL.	
	Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) 3-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment is made of applicant's election with traverse of Group I drawn to polypeptides, and the election of the species of SEQ ID NO:60. The traversal is on the grounds that the search for all the groups together would not be an undue burden. This has been considered but not found persuasive. The restriction was set forth as follows:

- I. Claims 1 and 2 drawn to substantially pure Bcl-XL binding polypeptides, classified in class 530, subclasses 300 and 350.
- II. Claims 3-8, drawn to the isolated nucleic acids encoding the polypeptides of Invention I, vectors and host cells thereof, classified in class 536, subclasses 23.5 and class 435, subclasses 252.3, 320.1 and 325.
- III. Claims 20-26 drawn to methods of source labeling a nucleic acid-fusion molecule, the source labeled nucleic acids and fusion proteins obtained thereby, and a method for identifying the source of the nucleic acid portion of said fusion molecule, class 435, subclass 91.5, class 536, subclass 23.1, class 530, subclass 402, and class 435, subclass 6.
- IV. Claims 9-19 drawn to method for identifying a Bcl-XL binding polypeptide comprising contacting a source labeled polypeptide with a Bcl-XL polypeptide and a method for identifying a compound that modulates the binding between a Bcl-XL polypeptide and a Bcl-XL-binding polypeptide, classified in class 435, subclass 7.1.

It is noted that all the groups are classified differently necessitating a separate search in the US patent shoes. Further, the literature search, particularly relevant in this art is not co-extensive and different patentability issues apply to each group. The examiner contends that it would be undue experimentation to search all of the pending groups. However, during the course of examination of the elected Group, it was noted that SEQ ID NO:60 was free of the prior art, and many of the other claimed SEQ NO were also free of the art. In order to advance prosecution, all claimed SEQ ID NO were searched within the scope of claims 1 and 2.

The restriction requirement is deemed proper and adhered to. The restriction requirement is therefore made final.

Claims 1-26 are pending. Claims 3-26, drawn to non-elected inventions, are withdrawn from consideration. Claims 1 and 2 are examined on the merits.

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Priority

Acknowledgement is made of applicant's claim to an earlier effective filing date through provisional application 60/274,526. Upon review of said provisional it was noted that the application lacked a written description of SEQ ID NO:224-228. Accordingly, claim 1 which incorporates the subject matter of SEQ ID NO:224-228 will be given the priority date of March 7, 2002 rather than the effective filing date of March 8, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially pure" in claims 1 and 2 is a relative term which renders the claim indefinite. The term "substantially pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a substantially pure human Bcl-xL-binding polypeptide, said polypeptide comprising the sequence selected from the group consisting of SEQ ID NO:4-50, 63-71 and 224-228. The specification states on page X, lines Y-Z that the instant invention encompasses peptides consisting of rather than "having" or "comprising" SEQ ID NO:4-50, 63-71 and 224-228. Thus, the amendment altering the scope of claim 1 to "comprising" has broadened the scope of the originally described invention. One of skill in the art would reasonably conclude that applicant was not in possession of the polypeptides "comprising" SEQ ID NO:4-50, 63-71 and 224-228 at the time the invention was filed.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Hammond et al (Journal of Biological Chemistry, Jun 2001, Vol. 276, pp. 20898-20906) or Giordano et al (CA 2,343,602) or Ruben et al (WO 01/22920).

Claim 1 is drawn in part to a substantially pure human Bcl-xL-binding polypeptide comprising SEQ ID NO:25.

Hammond et al (Journal of Biological Chemistry, Jun 2001, Vol. 276, pp. 20898-20906)

Hammond et al disclose the unknown protein encoded from clone V72, unknown protein encoded from clone Y37 and unknown protein encoded from clone Y01, wherein said unknown proteins are identical to SEQ ID NO:46, 33 and 48, respectively (page 2094, Table III)

Giordano et al (CA 2,343,602) disclose the polypeptide of SEQ ID NO:22815 which comprises SEQ ID NO:25 as evidenced by the attached Registry Number (599403-48-02) underlined portion.

Ruben et al (WO 01/22920) disclose the polypeptide of SEQ ID NO:5827 which comprises SEQ ID NO:25 as evidenced by the attached Registry Number (334566-32-4) underlined portion.

Neither Ruben nor Giordano et al specifically teach that the polypeptides bind to Bcl-xL, however, the claimed polypeptides appears to be the same as the prior art polypeptides, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed

product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al (WO 99/13075).

Claim 1 is drawn in part to a substantially pure human Bcl-xL-binding polypeptide comprising SEQ ID NO:25.

Zhu et al (WO 99/13075) disclose the protein p44 (Sequence Identifier No. 10, Registry No. 221221-63-2) which comprises SEQ ID NO:25 at residues 398-430. Zhu et al does not specifically disclose that the p44 protein would bind to Bcl-xL, however, it is recognized in the art that viruses express proteins which interfere with the normal onset of programmed cell death in order to propagate in the host.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Brissette et al (WO 03/38130) or Tang et al (WO 03/31595).

Claim 1 is drawn in part to a substantially pure human Bcl-xL-binding polypeptide comprising SEQ ID NO:18, SEQ ID NO:22 or SEQ ID NO:45..

Brissette et al (WO 03/38130) disclose a human 714 amino acid protein in Figure 3 comprising SEQ ID NO:18 at residues 555-582 as evidenced by that attached Registry structure (480644-87-9) and the SREBP-1 protein comprising SEQ ID NO:22 at residues at residues 594-620 as evidenced by that attached Registry structure (391970-32-4).

Tang et al (WO 03/31595) disclose the protein encoded by the human clone 784CIF2b_869 (Registry No. 352383-01-8) which comprises SEQ ID NO:45.

Neither Brissette et al nor Tang et al specifically disclose that the proteins binds to Bcl-xL, however, the claimed polypeptides appears to be the same as the prior art polypeptides, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the

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claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.


KARENA. CANELLA PH.D
PRIMARY EXAMINER